Department of State Health Services
Agenda Item for State Health Services Council
January 12 – 13, 2006

Agenda Item Title: New §§230.11 – 230.16 Rules Relating to Limitations on Sales of Products Containing Ephedrine, Pseudoephedrine, and Norpseudoephedrine

Agenda Number: 3e

Recommended Council Action:
____For Discussion Only

__X For Discussion and Action by the Council

Background: The Drugs and Medical Devices program of the Division for Regulatory Services regulates the manufacture and distribution of drugs and medical devices in Texas, including restrictions on the sales of controlled substances. The legislature passed a new statute in 2005 controlling the sales of ephedrine, pseudoephedrine, and norpseudoephedrine, and requiring the department to adopt rules to implement the legislation.

Summary: The new rules require retailers that wish to sell over the counter forms of ephedrine, pseudoephedrine, and norpseudoephedrine to obtain a Certificate of Authority, maintain security for the products, and maintain certain records regarding each purchase of the products, in order to lessen the diversion of these drugs to the illegal production of methamphetamine. The rules further provide information about exemptions, fees, and enforcement actions.

Summary of Stakeholder Input to Date (including advisory committees): An informal work group of manufacturers, distributors, retailers, law enforcement, and legislative staff, was established and the work group provided input into the development of the rules.

Proposed Motion: Motion to recommend to HHSC approval for publication of rules contained in agenda item # 3e.

Agenda Item Approved by: Rick Bays	**Date Submitted**
Presented by: Karen Tannert, R.Ph. **Title**: Pharmacist	**12/7/05**
Program/Division: Drugs and Medical Devices Group	
Contact Name/Phone: Susan Tennyson, 512-834-6770 X 2600	

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 230. Specific Additional Requirements For Drugs **[Average Manufacture Price and Purchase Price Reporting for Pharmaceuticals]**
Subchapter B. Limitations on Sales of Products Containing Ephedrine, Pseudoephedrine, and Norpseudoephedrine
New §§230.11 - 230.16

Proposed Preamble

The Executive Commissioner for Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §§230.11 - 230.16, concerning limitations on sales of products containing ephedrine, pseudoephedrine, and norpseudoephedrine.

BACKGROUND AND PURPOSE

These new sections are necessary to comply with Health and Safety Code (HSC), new Chapter 486, relating to the over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine. These subchapters require the department to adopt rules to implement and enforce the chapter. Under the new chapter, any business establishment (other than a pharmacy licensed by the Board of Pharmacy) that wishes to engage in over-the-counter sales of products containing any quantity of ephedrine, pseudoephedrine, or norpseudoephedrine must have a certificate of authority (COA) from the department. In order to obtain a COA, a business must: file an application with the department; pay the required fee; and agree to comply with the restrictions to access and record keeping requirements of these sections. Compliance with these sections will be verified through audits and inspections.

SECTION-BY-SECTION SUMMARY

The name of Chapter 230 of Title 25, Texas Administrative Code, was amended to reflect the addition of the new subchapter concerning the limitations on sales of products containing ephedrine, pseudoephedrine, and norpseudoephedrine. New §§230.11 - 230.16 set out the rules that limit the over-the-counter sales of these regulated products. Section 230.11 defines the purpose and definitions used in the rules. Section 230.12 sets out exemptions from licensing. Sections 230.13 and 230.14 explain the requirements for a COA to engage in over-the-counter sales of these products, and provide the minimum standards required to obtain and maintain the COA. Section 230.15 provides the records that must be maintained for each transaction involving the sale of these regulated products. Section 230.16 establishes the enforcement actions that can be taken to ensure that the rules are followed.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each fiscal year of the first five years the sections are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. The effect on state government will be an increase in revenue to the state of $1,125,000 the first fiscal year, and $750,000 each year for fiscal years two through ten due to the requirement for each retailer that engages in over-the-counter sales of regulated products to obtain a COA. These additional revenues will offset the costs associated with administering and enforcing these

sections. Implementation of the proposed sections will not result in any fiscal implications for local governments.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated economic costs to small businesses or micro-businesses required to comply with the sections as proposed. There will be a fee for businesses or persons required to obtain a COA. The probable economic cost to persons required to comply with the fee for the certificate will be $600 every two years for each retail establishment obtaining a certificate. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to reduce the diversion of regulated products that could be used to illegally manufacture methamphetamines.

REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by Government Code, §2001.0225. “Major environmental rule” is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rules do not restrict or limit an owner’s right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Tom Brinck, Drugs and Medical Devices Group, Environmental and Consumer Safety Section, Division for Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/719-0243 or by email to Tom.Brinck@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register.*

PUBLIC HEARING

A public hearing to receive comments on the proposal is scheduled for February 14, 2006, from 9:00 a.m. to 11:00 a.m. at the Department of State Health Services, Room K-100, 1100 West

49th Street, Austin, Texas 78756. For information, please contact Karen Tannert, R.Ph., at 512-834-6770, extension 2350.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Cathy Campbell, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed new sections are authorized by Health and Safety Code, §12.0111, which requires the department to charge fees for issuing or renewing a license; §12.0112, which requires the term of each license issued to be two years; and Health and Safety Code, §486.003, which authorizes adoption of rules necessary for the implementation and enforcement of Chapter 486; Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed new sections affect the Health and Safety Code, Chapters 12, 486, and 1001; and Government Code, §531.

Legend: (Proposed New Rule)
Regular Print = Proposed new language

§230.11. General Provisions.

(a) Purpose and applicability. The purpose of these sections is to implement the duties of the Department of State Health Services (department) under the Health and Safety Code (HSC), Chapter 486, relating to over-the-counter sales of ephedrine, pseudoephedrine, and norpseudoephedrine.

(b) Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Unless otherwise specified, the terms have the meaning assigned by HSC, Chapters 481 and 486, or their common use meaning.

(1) Business establishment -- A retail distributor such as a grocery store; general merchandise store; drug store; or other entity or person, other than a licensed pharmacy, that engages in direct sales to end-user consumers. A distributor who engages in greater than 5% of gross annual sales of regulated products to other than end-user consumers must obtain a license as a wholesaler under HSC, Chapter 431, Subchapter I or Subchapter N.

(2) Department -- The Department of State Health Services.

(3) Certificate of authority (COA) -- A grant of authority to engage in over-the-counter sales of regulated products, issued by the department to a person under this subchapter.

(4) Certificate of authority holder (COA holder) -- A person that has been issued a certificate of authority by the department to engage in over-the-counter sales of regulated products.

(5) Pharmacy -- A person holding a current license to operate a pharmacy issued by the Texas State Board of Pharmacy (Board of Pharmacy) under Occupations Code, Chapter 560.

(6) Record of sale -- The paper or electronic documentation prepared and maintained in compliance with §230.15 of this subchapter.

(7) Regulated products -- Any compound, mixture, or preparation containing any detectable amount of ephedrine, pseudoephedrine, or norpseudoephedrine, including its salts, optical isomers, and salts of optical isomers. The term does not include any compound, mixture, or preparation that is in liquid, liquid capsule, or liquid gel capsule form. A list of regulated products, by name and universal product code (UPC) or stock-keeping unit (SKU) identifiers, may be obtained from the Department of State Health Services, 1100 West 49th, Austin, Texas 78756, or online at www.dshs.state.tx.us/pseudoephedrine/list.

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(8) Over-the-counter sale -- The sale of not more than two packages or six grams of regulated products, in a single transaction to an individual.

§230.12. Exemptions. The following persons are exempt from the requirement to obtain a COA from the department before engaging in the sale of regulated products:

(1) a person licensed by the department under HSC, Chapter 431, Subchapters I or N, or who is specifically exempted from licensure under HSC, Chapter 431, Subchapters I or N;

(2) a person licensed as a pharmacist under Occupations Code, Chapter 558, who dispenses or delivers regulated products according to prescription issued by a practitioner for a valid medical purpose and in the course of professional practice; and

(3) a person licensed by the Board of Pharmacy to operate a pharmacy under Occupations Code, Chapter 560. Business establishments operating a licensed pharmacy must follow the requirements of the Texas State Board of Pharmacy and the provisions of HSC, Chapter 486. Those business establishments may not be issued a COA.

§230.13. Certificate of Authority.

(a) General.

(1) Except for persons who are exempt under §230.12 of this title (relating to Exemptions), a person is prohibited from engaging in over-the-counter sales of regulated products without a COA issued by the department under these sections.

(2) The grant of authority to sell regulated products under a COA confers only the right to sell regulated products in compliance with these sections.

(3) A COA is effective on the date of issuance and terminates on the expiration date. There is no implied or ongoing right or authority to sell regulated products beyond the expiration date on a COA.

(4) A COA confers no right or interest in property.

(5) A separate COA is required for each place of business.

(6) A COA cannot be conveyed, sold or transferred.

(b) Application. A person must submit an application for each place of business on a form, or in an electronic format through Texas Online (www.Texasonline.com), as prescribed by

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the department. Incomplete applications or applications submitted without the required fees will not be processed by the department. At a minimum the applicant must provide the following information:

(1) the name, home address, and business address of the applicant;

(2) the type of entity, whether sole proprietor, partnership, corporation, or other legal entity;

(3) the registered or trade name under which business is conducted;

(4) the name, residential address, and driver's license number of the person responsible for compliance with these rules at the place of business where regulated products will be sold, as well as all corporate officers, and all partners, if applicable;

(5) the normal business hours of the place of business;

(6) the name(s), address(es), and contact person(s) of the applicant's wholesale distributor(s);

(7) an indication of all health care products, by type, sold at the place of business;

(8) a list or inventory, including brand name, of all regulated products the applicant proposes to sell at the place of business;

(9) a detailed description of training provided to employees or other persons who will have access to; conduct sales of; and/or prepare records of sales of regulated products, including sales techniques and other measures designed to deter theft of regulated products; and

(10) written procedures on how regulated products will be kept; whether behind a sales counter, or in a locked display case within 30 feet and in the direct line of sight of a sales counter continuously staffed by an employee.

(c) Fees. The fee for a COA is $600 for a two-year license. All fees, including any late fee or past due fee, must be paid before a COA will be issued. All fees are non-refundable.

(d) Term and expiration. The term of a COA is two years. The department may stagger the expiration dates of COAs issued under theses sections. The department determines the expiration date. The grant of authority to sell regulated products ends on the expiration date indicated on a COA. Any sale under an expired COA is a violation of HSC, Chapter 486, and these rules.

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(e) Renewal. The department may renew a COA only if the COA holder is in substantial compliance with these sections. A COA holder must submit a renewal application along with the required fee before the expiration date on the current certificate to avoid a lapse in authority to sell regulated products under these sections.

§230.14. Minimum Standards for Certificate of Authority.

(a) Criminal history of applicant. A COA may be denied to an applicant if the applicant, or a partner, or a corporate officer, or the person responsible for business operations such as a manager, has been convicted of an offense related to the manufacture or sale of illegal drugs or has been convicted of any felony reasonably related to the COA requested.

(b) Failures or omissions. A COA may be denied to an applicant who:

(1) has furnished material information in an application that is false, fraudulent, or misleading;

(2) has failed to establish or maintain effective theft prevention and deterring measures;

(3) has failed to maintain records required to be kept by §230.15 of this title (relating to Records);

(4) has refused to allow an inspection as authorized by HSC, Chapter 486, or refused or failed to produce required records for inspection; or

(5) has violated HSC, Chapter 486, or these rules.

(c) Theft prevention and deterring measures.

(1) A COA holder shall maintain regulated products behind a sales counter or in a locked case within 30 feet and in direct line of sight from a sales counter continuously staffed by an employee.

(2) A COA holder must document and implement sales techniques and other measures designed to deter the theft of regulated products and other products commonly used in the illicit manufacture of methamphetamines. Written procedures must be developed by the COA holder to include:

(A) security of regulated products, including receiving at the business; storage in the stockroom or other storage facility; and stocking of the sales counter or locked display cabinet;

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(B) measures to ensure that employees and other staff who have a criminal drug history do not have access to regulated products; and

(C) measures to ensure that regulated products cannot be accessed without the assistance of an authorized employee of the business.

§230.15. Records.

(a) Before completing a sale of a regulated product, an employee with authority to access regulated products must:

(1) require the person making the purchase to:

(A) display a driver's license or other form of government identification containing the person's photograph and indicating that the person is 16 years of age or older; and

(B) sign for the purchase;

(2) make a record of the sale, using a format approved or provided by the department for this purpose, that includes the name of the person making the purchase, the date of the purchase, and the item purchased by UPC or SKU; and

(3) take reasonable measures to limit single sales transactions to:

(A) two packages of a regulated product; or

(B) UPC or SKU codes that, when totaled, contain no more than 6 grams of ephedrine, pseudoephedrine, or norpseuodoephedrine base.

(b) The COA holder must maintain these records at the business establishment for a minimum of two years from the date the record is made.

(c) The COA holder must make the records available to the agent(s) of the Department of State Health Services or the Department of Public Safety upon request.

§230.16. Enforcement.

(a) The department may impose an administrative penalty for a violation of HSC, Chapter 486, or these rules.

(b) The amount of the administrative penalty may be up to $1000 per violation per day, not to exceed $20,000 for a violation of a continuing nature.

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(c) The amount of the penalty is based on:

(1) the seriousness of the violation;

(2) the threat to health or safety caused by the violation;

(3) the history of previous violations;

(4) the amount necessary to deter a future violation;

(5) whether the violator demonstrated good faith, including good faith efforts to correct the violation; and

(6) any other matter that justice may require.

(d) The department may revoke a COA for a violation of HSC, Chapter 486, or these rules. The department may also revoke a COA if the COA holder is convicted of any offense related to the manufacture or distribution of illegal drugs.

(e) A request for a hearing by a COA holder in response to a notice of violation will be referred to the State Office of Administrative Hearings. An informal enforcement conference with the department may be held prior to a hearing to dispose of all matters related to the notice of violation.

(f) Failure to respond within 15 days to a Notice of Violation letter issued by the department may result in the factual allegations listed in the notice being deemed admitted, and the relief sought in the notice of hearing may be granted by default. The Commissioner of the Department of State Health Services or his designee may sign the default order.

(g) Hearings at the State Office of Administrative Hearings are governed by the procedures in Government Code, Chapter 2001, and by Health and Safety Code, Chapter 486.

Health and Human Services
Enterprise

Rulemaking Fiscal Impact

June 2005

Agency Unit/Section/Division Dept. of State Health Services/Policy, Standards and Quality Assurance Unit/Environmental and Consumer Safety Section/Regulatory Services Division	Council Meeting Date January 12, 2006
Agency Program Contact: Susan Tennyson	Telephone No. (512) 834-6770 ext. 2600
Rule Topic 25 TAC §230.11-230.16, concerning rules relating to limitations on sales of products containing pseudoephedrine, ephedrine, and norpseudoephedrine	

1. Rule Summary.

(Briefly summarize the rule change and why the rule may or may not have fiscal implications.)

The Texas Legislature passed House Bill 164, 79th Legislature, Regular Session, (2005). Section 9 of the Bill adds new Chapter 486 to the Health and Safety Code, regulating the over-the-counter sales of pseudoephedrine, ephedrine, and nor-pseudoephedrine drug products. New §486.003 authorizes the council to adopt rules necessary to implement and enforce the chapter. The proposed rules have fiscal implications due to new fees established for certificates of authority.

2. Fiscal Impact.

Does the rule have foreseeable fiscal implications to either costs or revenues of state government for the first five years the rule is in effect?

☒ **Yes** ☐ **No** If yes, complete the following:

(a) If there are estimated additional costs to the department, explain (1) what new responsibilities will be required; (2) what additional staff will be needed (numbers and classifications); and (3) what other expenses, such as capital or professional services, will be required. Explain any key assumptions that will be needed to reach the figures in the chart in 2(d).

Certificate holders will need to be inspected routinely every year by the department to ensure compliance with the rule requirements. Inspectional findings will be documented in reports and subsequently reviewed by program staff to determine if enforcement action is necessary. Licensing and administrative support staff, compliance officers and group managers will be required to process and issue certificates of authority, review and endorse inspection reports, and make recommendations for necessary enforcement action.

(b) If there is an estimated reduction in costs, explain how the reductions will be accomplished.

N/A

(c) If there is an estimated increase in revenue, describe the source and amount. If there is an estimated loss of revenue, describe the source and amount.

Concerning 25 TAC 230.11-230.16, there is an estimated increase in revenue of $1,125,000 in 06 and $750,000 in 07 through 10 from fees for Certificates of Authority (COAs).

Note: Staff may provide the information in (d) on a separate spreadsheet. If spreadsheet is attached, please check here: ☒

(d)

	1. Fiscal Year 2006	2. Fiscal Year 2007	3. Fiscal Year 2008	4. Fiscal Year 2009	5. Fiscal Year 2010
Estimated Additional/Reduction in Cost (specify reduction in parenthesis)					
STATE FUNDS	214,905	749,860	749,860	749,860	749,860
FEDERAL FUNDS					
OTHER FUNDS					
TOTAL:	214,905	749,860	749,860	749,860	749,860

Estimated Increase/Loss of Revenue (specify loss in parenthesis)					
STATE FUNDS	1,125,000	750,000	750,000	750,000	750,000
FEDERAL FUNDS					
OTHER FUNDS					
TOTAL:	1,125,000	750,000	750,000	750,000	750,000

3. Local Government Impact.

Does the rule have foreseeable positive or negative fiscal implications to either costs or revenues of local governments for the first five years the rule is in effect?

☐ **Yes** ☒ **No** If yes, enter the amounts for each of the five years and explain key assumptions you used to reach the figures.

4. Small Businesses or Micro-Businesses Impact.

Does the rule have ANY adverse economic effect on small businesses or micro-businesses* (regardless of whether it will have an adverse effect on businesses in general)?

☒ **Yes** ☐ **No** If **yes**, complete **4B–E**. If **no**, complete **4A**.

* A small business is a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has fewer than 100 employees OR less than $1,000,000 in annual gross receipts.

A micro-business is a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has 20 or fewer employees.

A. If the rule **will not** have an adverse economic effect on either small businesses or micro-businesses, or both, explain why there will be no adverse effect on one or both.

N/A

Complete (B)-(E) if rule will have an adverse economic effect on small businesses or micro-businesses or both.

Note: You must discuss both small businesses and micro-businesses in your analysis regardless of whether the rule will have an adverse economic effect on either one or both.

B. Explain why there will be an adverse economic effect, such as new fees, reduced revenues, or new regulatory requirements that will increase the cost of doing business.

The proposed rule will establish new fees associated with the over-the-counter sales of pseudoephedrine, ephedrine, and nor-pseudoephedrine containing drug products.

C. Give an analysis of the cost to small businesses or micro-businesses of complying with the rule. Explain what assumptions you used to calculate these projected costs (for example, a survey of randomly selected assisted living facilities).

Concerning 25 TAC §230.11-230.16, retailers of over-the-counter pseudoephedrine, ephedrine, and nor-pseudoephedrine containing drug products that are small businesses will be required to obtain a Certificate of Authority (COA) from the department at a cost of $600 for a two-year certificate.

D. Compare the cost to small businesses or micro-businesses of complying with the rule with the cost to the largest businesses affected by the rule, analyzing, when possible:

- cost per employee,
- cost per hour of labor, or
- cost per each $100 of sales.

Concerning 25 TAC §230.11-230.16 – the fees for obtaining a COA are the same regardless of business size.

E. Give an analysis of whether it is legal and feasible to reduce the economic effect of the rule on small businesses or micro-businesses, while still accomplishing the intent of the state or federal law being implemented with the rule.

Concerning 25 TAC §230.11-230.16, the fees for obtaining a COA are the same regardless of the business size. Chapter 486, Health and Safety Code requires anyone selling pseudoephedrine, ephedrine, and nor-pseudoephedrine containing drug products to comply with the requirements of the statute, regardless of the size of the business. The statute also directs the department to recover the costs associated with issuing a COA, inspecting a place of business and ensuring compliance with the minimum standards established by the department. The statute does not allow for exceptions based on the business size of the certificate holder.

5. Other Cost Impacts.

If there will be costs to persons who must comply with this rule change, other than costs identified in preceding sections, enter estimated costs for the first five fiscal years of implementation:

FY 1	FY 2	FY 3	FY 4	FY 5

Explain assumptions used to arrive at these costs.

N/A

6. Fiscal Impact on Local Employment:

☒ Rule **will not** have an impact.

☐ Rule **will** have an impact. You must complete an Economic Impact Request and submit it to TWC at least 30 days before the Council meeting.

7. Takings Impact Assessment.

Does the proposed rule create a burden on private "real property" (i.e. real estate or the buildings and other structures attached to real estate)?

☐ **Yes** ☒ **No** If **yes**, contact Legal **immediately** to determine if you are required to complete a Takings Impact Assessment.

Approvals

Signature – Budget Analyst (original signature on file)	Date	Telephone No.
Signature – Budget Director (original signature on file)	Date	Telephone No.
Signature – Chief Financial Officer (original signature on file)	Date	Telephone No.
Signature – Deputy Executive Commissioner (as appropriate) (original signature on file)	Date	Telephone No.